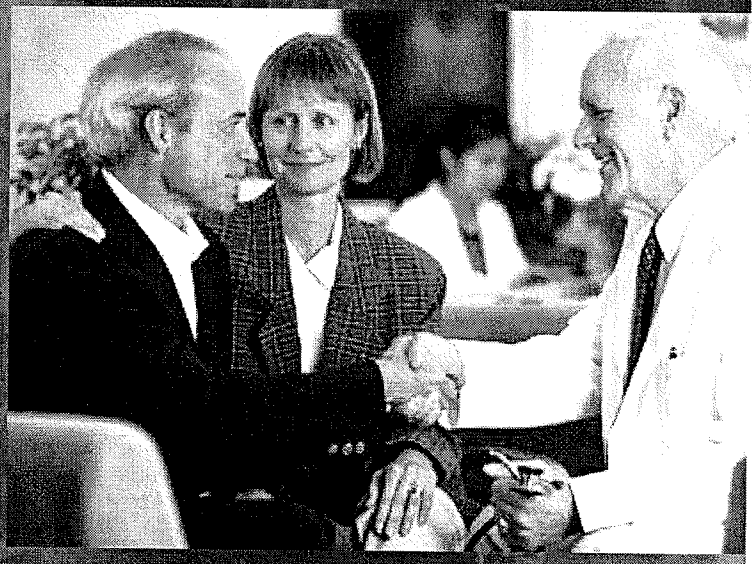
Xience™ V

Everolimus Eluting Coronary Stent System



Patient Information Guide

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Abbott
A Promise for Life

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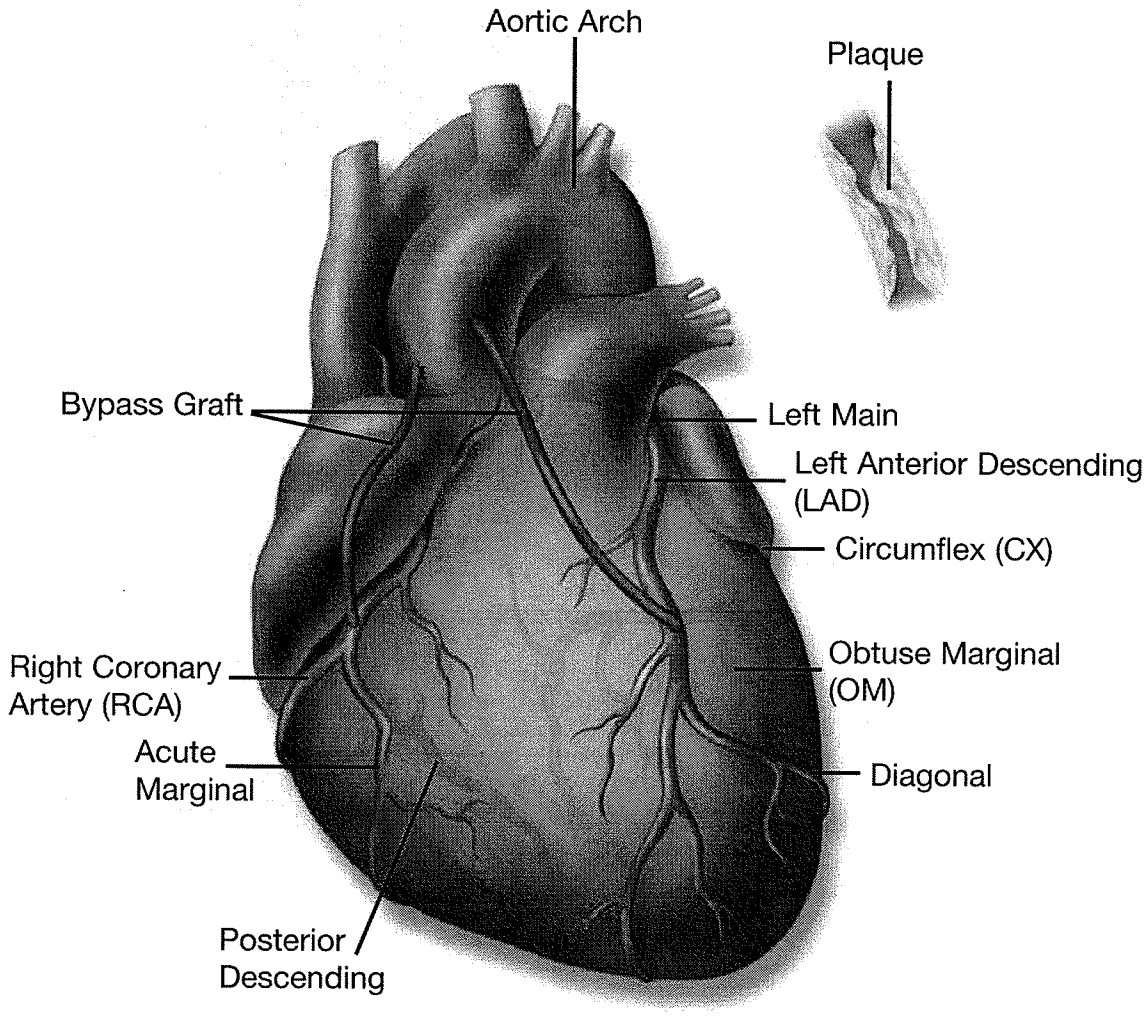
Coronary Vasculature



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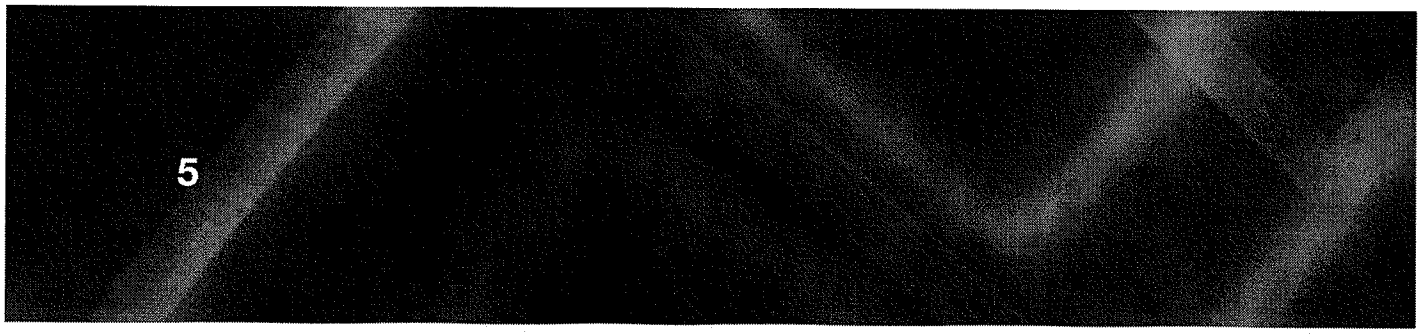
Coronary Artery Disease (CAD)

Your Heart

Your heart is a muscle that pumps blood throughout your body. The blood carries oxygen and nutrients that your body needs to work correctly. For the heart to be able to function properly, it also needs a constant supply of oxygen-filled blood. The vessels that supply this blood to the heart are called coronary arteries. If these arteries become blocked or narrowed, treatment may be required to restore blood flow and the vital supply of oxygen to the heart.

What is Coronary Artery Disease (CAD)?

CAD is the most common form of heart disease. It is a condition that occurs when the arteries that supply oxygen-rich blood and nutrients to the heart muscle become narrowed or blocked by a gradual build-up of "plaque." Plaque is made up of fatty deposits (cholesterol), white blood cells, calcium, and other substances that collect over time in the wall of a coronary artery. As the plaque narrows the opening (lumen) of a coronary artery, it makes it difficult for adequate quantities of blood



Coronary Artery Disease (CAD) *(continued)*

to flow to the heart muscle. This process is called "atherosclerosis." Gradual reduction of blood flow to the heart muscle can cause chest pain (angina). A heart attack (myocardial infarction) can occur if the artery suddenly becomes completely blocked, usually by a blood clot that forms over ruptured (broken) plaque. Heart attacks cause irreversible damage to the heart muscle. The first symptom of CAD can also be sudden death.

Improved medical treatment, combined with earlier diagnosis, and increased public awareness of the symptoms and risk factors that contribute to this disease are helping to decrease the death rate from CAD.

What are the Symptoms of CAD?

Two common symptoms of CAD are chest pain, also known as angina, and shortness of breath, which are caused by the reduction of blood flow to the heart muscle. If plaque build-up does not reduce blood flow excessively, there may be no noticeable

Coronary Artery Disease (CAD) *(continued)*

symptoms at rest, but symptoms such as heaviness in the chest may occur with increased activity or stress.

Other symptoms that may be experienced are:

- Pain in the jaw or neck
- Pain radiating to the arms or back
- Heartburn
- Nausea
- Vomiting
- Heavy sweating

When blood flow is significantly reduced and the heart muscle does not receive enough blood to meet its needs, severe symptoms such as chest pain (angina pectoris), heart attack (myocardial infarction), or heart rhythm disturbances (arrhythmias) may occur.

There are some patients who report no symptoms of CAD. It is possible to have a heart attack without experiencing any symptoms.

Coronary Artery Disease (CAD) *(continued)*

Recent research has shown that some women experience different CAD symptoms from men and are less likely than men to report chest pain, heaviness in the chest, or chest discomfort during a heart attack. Women may notice other early symptoms, such as unusual tiredness or sleep disturbances up to one month prior to a heart attack. These differences in symptoms may cause some women to delay seeking help or treatment.

What are the Risk Factors of CAD?

Two main risk factors for CAD are:

- Increasing age (over age 65)
- Being male or a menopausal female[1]

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[1]Menopausal women begin to develop and die of heart disease at a rate equal to men. Menopause is the transition in a woman's life when production of the hormone estrogen in the body falls permanently to very low levels, the ovaries stop producing eggs, and menstrual periods stop.

Coronary Artery Disease (CAD) *(continued)*

Other risk factors that may increase your chances of developing CAD are:

- Family history of heart disease (close relatives with heart disease at a young age)
- Diabetes
- High blood cholesterol levels
- Smoking
- High blood pressure
- Stress
- Obesity (being overweight)
- High fat diet
- Lack of exercise

How Can My Doctor Tell if I Have CAD?

If your doctor suspects that you have CAD or if you have symptoms of the disease, he/she will ask you about your risk factors and your symptoms. A complete physical exam and blood tests to identify injury to your heart muscle will also be completed. In addition, some of the tests used to make the diagnosis are:

Coronary Artery Disease (CAD) *(continued)*

Electrocardiogram (ECG/EKG) is a commonly used test that records your heart's electrical activity and can show certain problems such as abnormal heartbeats or damage to the heart muscle. An ECG can be done at rest or while you are walking or running on a treadmill or pedaling a stationary bicycle (Stress ECG).

Stress Tests are used to evaluate your heart rate, heart rhythm, and ECG while you are exercising. The results of a stress test can help your doctor determine the areas of heart muscle which are affected by lack of blood flow due to CAD.

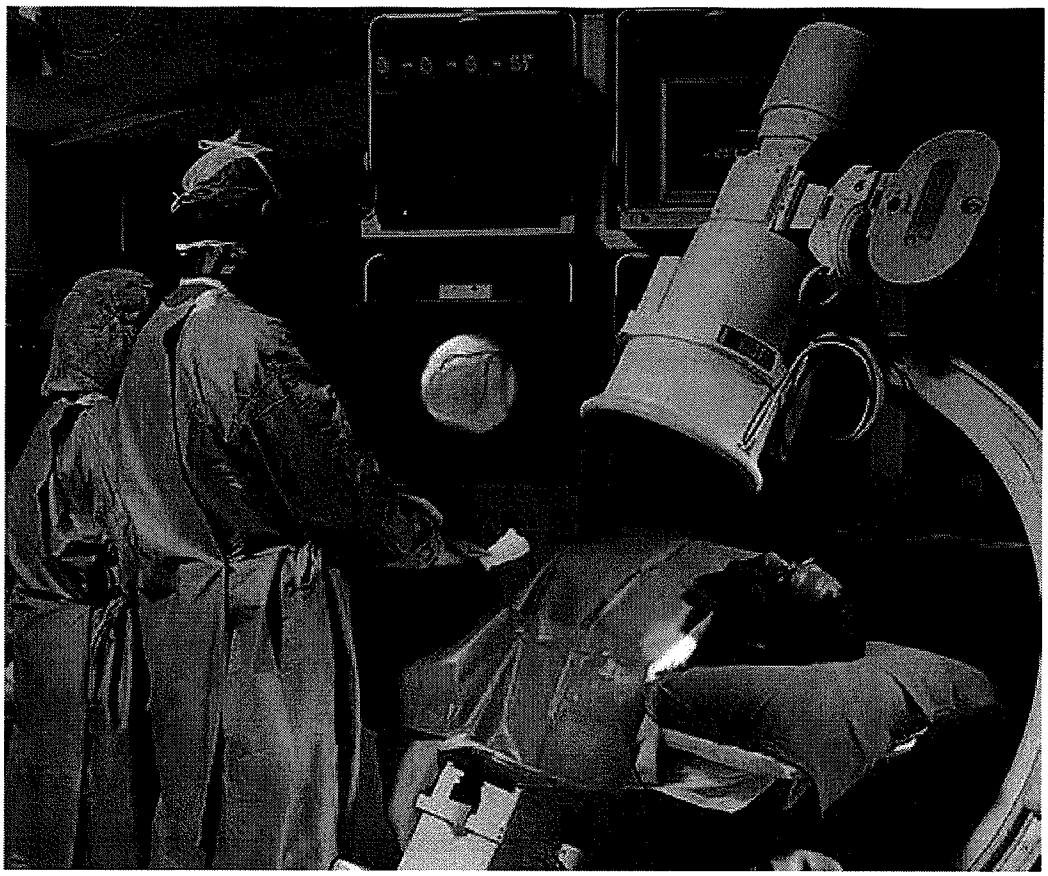
Echocardiography is an exam of the heart using sound waves.

Coronary Angiogram or Heart Catheterization is a procedure carried out in the cardiac catheterization laboratory (cath lab) by a cardiologist. Angiography is a procedure in which coronary arteries are visualized using X-rays.

Coronary Artery Disease (CAD) *(continued)*

A catheter (long, thin, hollow tube) is inserted into an artery in the groin or arm. The tip of this tube is positioned at the beginning of the arteries supplying blood to the heart, and a special fluid called contrast dye is injected through the tube to visualize the blood vessels on X-rays so that pictures, called angiograms, can be taken. These angiograms allow the doctor to see any blockage and/or narrowings in your coronary arteries and determine their severity.

Using the information gathered from one or more of these tests, your doctor is better able to decide the best treatment plan for you.



Cardiac Catheterization Laboratory

Your Treatment Options

Once a diagnosis has been made, your doctor will recommend the most appropriate form of treatment, depending on the condition and severity of your CAD. CAD can be managed by a combination of changes in lifestyle (eating a healthy, low-saturated fat diet, regular exercise, and quitting smoking) and medical treatment. Your treatment may include medications to relieve your chest pain and/or to expand the coronary arteries, increasing blood flow to your heart.

However, because medicine alone may not clear blocked arteries, you may need more treatment, including surgery, angioplasty, and/or stenting to treat your symptoms.

Your doctor will explain the risks and benefits of your treatment options and answer any questions you or your family may have. You are encouraged to discuss your treatment options with your doctor.

Your Treatment Options *(continued)*

Surgery

Coronary artery bypass grafting is a common surgical procedure that removes a section of artery or vein from another part of your body. This vessel is then connected (grafted) to the coronary artery at the blockage site. This creates a new path for blood to flow around (bypass) the blocked artery and to your heart. Often, several blocked arteries are bypassed during the same operation. Most coronary bypass patients remain in the hospital for about a week, followed by a recovery period at home.

Angioplasty

Angioplasty is a procedure used to open blocked arteries. You may also hear it referred to as PTCA (Percutaneous Transluminal Coronary Angioplasty). This procedure is performed under local anesthetic in a cardiac catheterization laboratory. A catheter with a small balloon mounted on the end is passed into the coronary artery. The catheter is then positioned at the narrowed portion of the artery and the balloon is inflated. As the balloon inflates, it pushes out against the wall of the coronary artery and compresses the plaque. The balloon is then deflated and the catheter

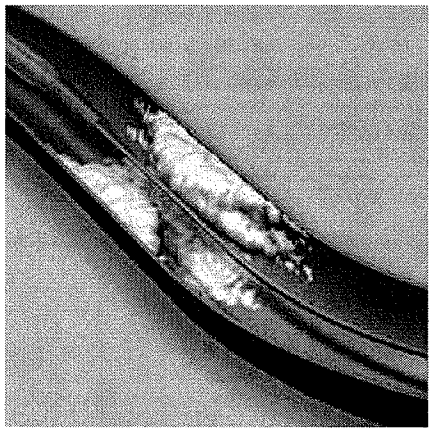
Your Treatment Options *(continued)*

is removed from the artery. This opens the narrowing in the coronary artery and improves the blood flow to the heart muscle. In balloon angioplasty, no permanent device remains in the artery after the balloon catheter is removed. Balloon angioplasty can be performed with a balloon alone or can involve placement of a permanent device called a stent, within the coronary artery.

Although balloon angioplasty enlarges the lumen of coronary arteries, many patients develop re-narrowing of the vessel in the months following the procedure. This process is called restenosis, and it is caused by the growth of scar tissue within the coronary artery.

Step 1:

The doctor guides a catheter with a small balloon through the blood vessel to the narrowed section of the artery. By watching the progress of this catheter on the fluoroscope (an X-ray device that creates real-time images



Step 1

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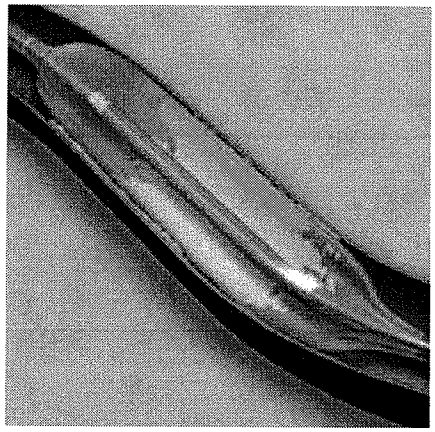
Your Treatment Options *(continued)*

of the internal structures of the body that can be viewed on a TV monitor), the doctor is able to maneuver it into the blocked coronary artery.

Step 2:

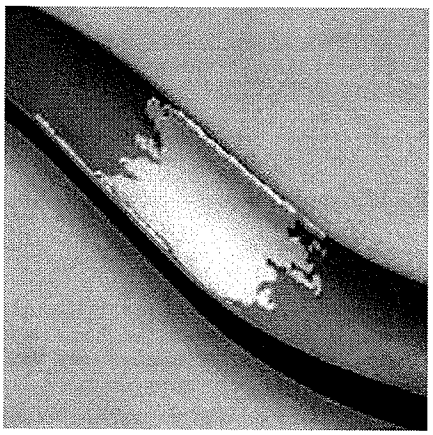
The balloon is inflated, pushing out against the wall of the artery and compressing the plaque. The balloon is deflated and the catheter is removed.



Step 2

Step 3:

The inside of the blood vessel is now larger and the blood flow is improved.



Step 3 A2897

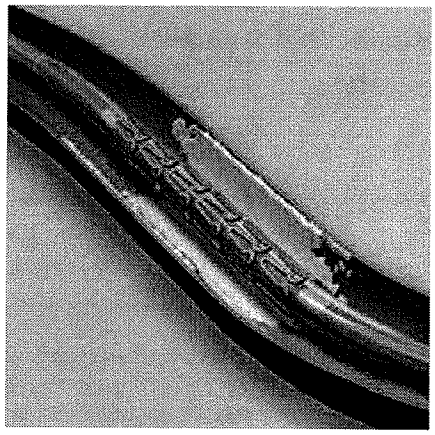
Your Treatment Options *(continued)*

Coronary Artery Stents

Coronary artery stents are devices (small metallic mesh tubes) that are placed over a balloon catheter and delivered to the narrowed portion of the coronary artery. The balloon is used to expand the stent. The stent presses against the narrowed vessel wall holding the vessel open. This makes a wider channel to improve blood flow to the heart muscle. This may be followed by repeat balloon inflations within the stent to achieve the result desired by your doctor. Once the balloon has been deflated and withdrawn, the stent stays in place permanently, holding the coronary artery open. The inner lining of the artery grows over the surface of the stent, making the stent a permanent part of your artery.

Step 1:

The doctor maneuvers the catheter into the blocked artery and inflates the balloon.

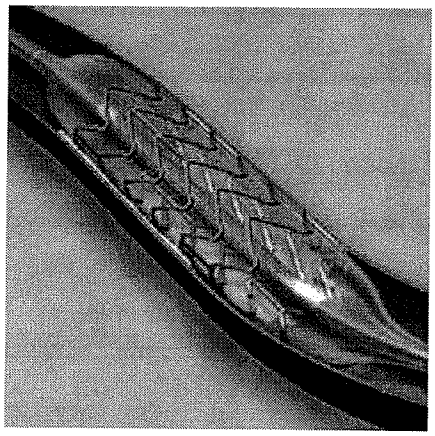


Step 1 A2898

Your Treatment Options *(continued)*

Step 2:

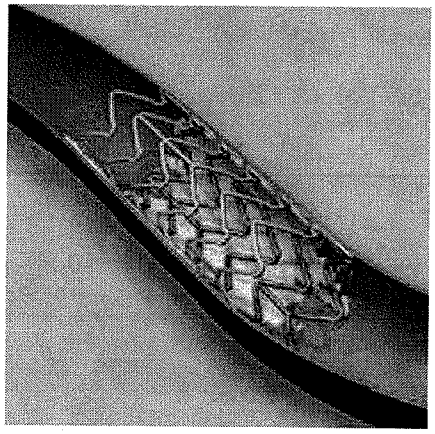
The stent expands against the vessel wall as the balloon is inflated.



Step 2

Step 3:

Once the balloon has been deflated and the catheter is withdrawn, the stent stays in place permanently, holding the blood vessel open and improving blood flow.



Step 3

Coronary artery stents are less invasive than bypass surgery. Stenting involves a shorter hospital stay — usually one to three days — and faster recovery than surgery. However, restenosis can also occur in some patients who receive stents (in-stent restenosis) due to the build-up of scar tissue within the stent leading to narrowing of the stent lumen.

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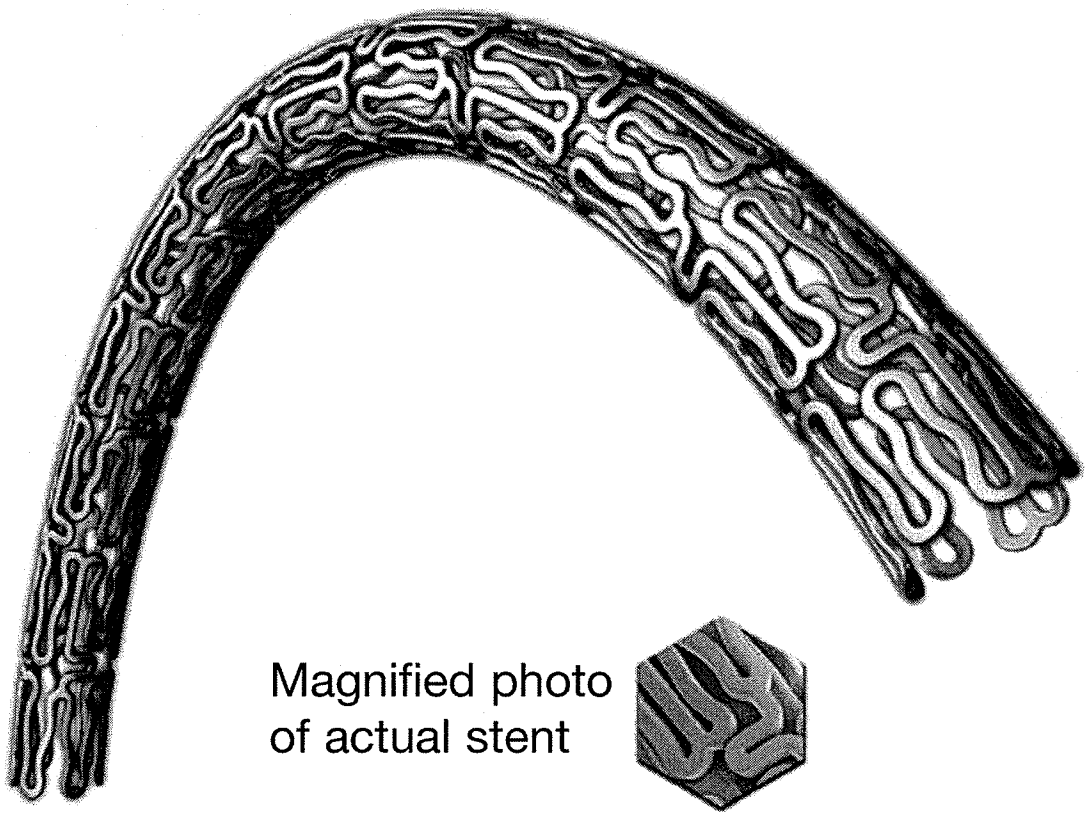
Drug Eluting Stents (DES)

To help prevent restenosis, "drug-eluting" stents have been developed. These stents provide the same structural support as uncoated stents, but they also have a drug coated on them. The drug is released over time, helping to prevent restenosis by limiting the overgrowth of normal tissue within the stent.

XIENCE V Everolimus Eluting Coronary Stent System

The illustration shown is an artist's rendition of Abbott's drug eluting stent, the XIENCE V.



Magnified photo of actual stent

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XIENCE V Everolimus Eluting Coronary Stent System *(continued)*

The XIENCE V stent is designed to prevent re-narrowing within the stent (in-stent restenosis). It consists of a medical grade cobalt chromium stent with a thin coating of a drug called everolimus on its surface. This stent is based on the design of the clinically proven MULTI-LINK VISION® stent and provides mechanical support to the artery while everolimus is slowly released into the artery wall around the stent from a thin polymer (a type of plastic) coating. The polymer coating helps control the release of everolimus into the arterial wall. The polymer used on the XIENCE V stent has a long history of being used in medical products in contact with blood. The release of everolimus is intended to limit the overgrowth of tissue within the coronary stent.

A2902

XIENCE V Everolimus Eluting Coronary Stent System *(continued)*

Contraindications:

- If you have a known hypersensitivity (allergy) or contraindication to everolimus or structurally-related compounds cobalt, chromium, nickel, tungsten, acrylic, and fluoropolymers
- If you cannot take aspirin or blood-thinning medications (also called antiplatelet or anticoagulant therapy)
- If your physician decides that the coronary artery blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent

A2903

Potential Adverse Events Associated with the XIENCE V Stent

The risk of using the XIENCE V stent is similar to those that are associated with standard stent procedures. If the stent clots, you may need another angioplasty procedure. It may also lead to a heart attack, the need for urgent bypass surgery, or death. Even with successful stent implants, there is a chance of re-narrowing of your coronary artery. This may require further treatments, such as repeat angioplasty and/or bypass surgery, to reopen the artery and to increase blood flow to the heart. The risks from using balloon catheters after stent implants are similar to the risks that may occur during the initial stent implant. These may be serious enough to require surgery or cause death.

Other risks from these devices are the same as treatment procedures for a narrowed coronary artery. Some problems associated with standard balloon angioplasty and stenting include, but are not limited to:

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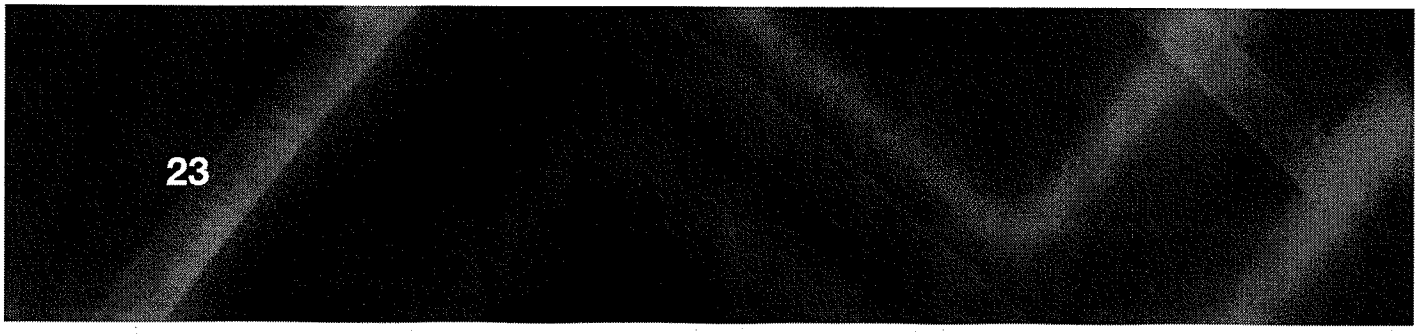

Potential Adverse Events Associated with the XIENCE V Stent *(continued)*

Common Risks

- Bruise or bleeding at the catheter insertion site in the groin or arm
- Pain at the catheter insertion site
- Irregular heartbeats
- Chest pains during and after the procedure
- Spasm of the coronary artery
- Decreased or increased blood pressure

Rare Risks

- Tearing, puncture, or rupture of the coronary artery
- Air, pieces of devices, or fragments of clots blocking the coronary or peripheral arteries
- Complete blockage of the coronary artery, which may require a repeat procedure to reopen the coronary artery
- Compression of the heart due to accumulation of blood around the heart
- Re-narrowing of the coronary artery
- Heart attack

A2905

Potential Adverse Events Associated with the XIENCE V Stent *(continued)*

- Damage to the stent or injury to the coronary artery, requiring emergency heart surgery
- Bleeding, requiring transfusion or surgery
- Allergic reaction (may include X-ray dye, cobalt, chromium, nickel, tungsten, everolimus, acrylic, and fluoropolymer)
- Infection
- Nerve injury
- Kidneys fail to function normally
- Aneurysm (weakening of a portion of the wall of a blood vessel)
- Shock
- Stroke
- Death

A2906

Potential Adverse Events Associated with the XIENCE V Stent *(continued)*

Potential adverse events related to taking everolimus daily by mouth (based on long-term everolimus drug studies in organ transplant patients) may include:

Acne, decreased red or white blood cells, blood clotting abnormalities, diarrhea, water retention in the body, destruction of red blood cells, increased blood cholesterol, increased fat in the blood, increased blood pressure, decreased functioning of sexual organs in men, infections, liver function test abnormality, white blood cell abnormalities, nausea, pain, rash, destruction of the kidney tubules, surgical wound complication, decreased platelet cell count, blood clot in the vein, or vomiting.

Exposure to drug and polymer on the XIENCE V stent is directly related to the number and lengths of the stents implanted. The use of multiple XIENCE V stents will result in you receiving larger amounts of drug and polymer. It should be noted that a kidney transplant patient usually receives a daily dose of the drug everolimus by mouth that is about seven times more than the maximum dose of the drug contained on one XIENCE V stent.

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Potential Adverse Events Associated with the XIENCE V Stent *(continued)*

Everolimus, when given by mouth daily to organ transplant patients, may interact with other drugs or substances. Please tell your physician about any medications you are taking.

The XIENCE V SPIRIT Family of Clinical Trials

There have been three clinical trials thus far that together have shown the safety and effectiveness of the XIENCE V drug eluting stent in patients with coronary artery disease. A short description of these trials, known as the XIENCE V SPIRIT Family of Trials, is detailed below.

SPIRIT FIRST

SPIRIT FIRST was the first clinical trial. This study had 60 patients and was performed outside the United States. The purpose of the study was to compare the XIENCE V stent that is coated with a drug to that of an approved metallic stent that is not coated with a drug. There were 28 patients who received the XIENCE V stent and 32 patients who received the metallic stent (patients who received the metallic stent are also known as the "control" group).

After six months, the XIENCE V stent was significantly better than the metallic stent at reducing the re-narrowing of the artery where the stent was placed. After three years, patients who had received

The XIENCE V SPIRIT Family of Clinical Trials *(continued)*

the XIENCE V stent had fewer major adverse cardiac events (15.4%) compared to patients who received the metallic stent (25.0%).

SPIRIT II

The SPIRIT II clinical trial was the second study of the XIENCE V stent. The purpose of the study was to compare the XIENCE V stent to an approved drug eluting stent, called TAXUS®. The SPIRIT II study was conducted outside of the United States.

After six months, the XIENCE V stent was significantly better than the TAXUS stent at reducing the re-narrowing of the artery where the stent was placed. At two years, patients who had received the XIENCE V stent had a rate of major adverse cardiac events (6.6%) that was comparable to the TAXUS stent (11.0%).

The XIENCE V SPIRIT Family of Clinical Trials *(continued)*

SPIRIT III

SPIRIT III was the third clinical study of the XIENCE V stent. This was a much bigger study than either the SPIRIT FIRST or SPIRIT II studies, and was conducted in the United States. In one part of this study, 1002 patients were given either the XIENCE V stent or the TAXUS stent. There were 669 patients who received the XIENCE V stent and 333 patients who received the TAXUS stent.

After eight months, the XIENCE V stent was significantly better than the TAXUS stent at reducing the re-narrowing of the artery where the stent was placed. At one year, patients who had received the XIENCE V stent had a rate of major adverse cardiac events (6.0%) that was comparable to the TAXUS stent (10.3%).

For patients treated with the XIENCE V stent in ways not studied in these clinical trials, clinical results may vary. Very long-term (beyond 24 months) risks and benefits associated with the XIENCE V stent are currently unknown.

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